DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

May 2, 2015

Bio-Detek, Inc.
% Tanmay Shukla
Sr. Regulatory Affairs Specialist
Zoll Medical Corporation
269 Mill Road
Chelmsford, Massachusetts 01824-4105

Re: K150055
Trade/Device Name: OneStep Pediatric CPR Multi-function Electrode
Regulation Number: 21 CFR 870.5310
Regulation Name: Automated External Defibrillator
Regulatory Class: Class III
Product Code: MKJ, LIX
Dated: April 3, 2015
Received: April 6, 2015

Dear Tanmay Shukla:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply

with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Section 4 – Indications for Use

510(k) number (if known): _____

Device Name: OneStep Pediatric CPR Multi-Function Electrode

Intended Use:

- Defibrillation
- Cardioversion
- Noninvasive Pacing
- ECG Monitoring
- CPR Feedback

For use with **ZOLL®** Defibrillators, such as:

- R Series
- X Series

Trained Personnel only, Including:

- Physicians
- Nurses
- Paramedics
- Emergency Medical Technicians
- Cardiovascular Laboratory Technicians

The OneStep Pediatric CPR electrodes are indicated for use on a patient less than 8 years of age or weighing less than 55 lbs (25kg).

Prescription Use __X__ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use ____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

BIO-DETEK
INCORPORATED

510(k) Summary:

Submitter's Name and Address:
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Date Summary Prepared:
January 9, 2015

Device Name / Proprietary Name:
ZOLL OneStep Pediatric CPR Multi-Function Electrode (MFE)

Common Name:
Automated External Defibrillator Multi-Function Electrodes

Classification Name:
Multi-Function Electrode, with CPR Aid
Accessory to an Automated External Defibrillator (21 CFR 870.5310 – Product Code MKJ)

Substantial Equivalence:
ZOLL OneStep Pediatric CPR MFE (K120907)
OneStep CPR II MFE (K133441)

Description of Device:

As with the currently marketed OneStep Pediatric CPR Multi-Function Electrode (reviewed and cleared with K120907), the modified OneStep Pediatric CPR Multi-Function Electrode (MFE) is intended for use with ZOLL R Series and ZOLL X Series defibrillators for ECG Monitoring, Defibrillation, External Noninvasive Pacing, Cardioversion and CPR Feedback for use on patient less than 8 years of age or weighing less than 55lbs (25kg) in either the hospital or pre-hospital environment. The currently marketed OneStep Pediatric CPR MFE provides users with accurate depth compression feedback when CPR is performed on a firm surface – a known recommended practice. A recent publication by the AHA acknowledges that "accelerometers are insensitive to mattress compression" and stresses the need for "continued development of optimal and widely available CPR monitoring." So, with the current submission, we are proposing to modify the OneStep Pediatric CPR MFE to incorporate a second motion sensor on the posterior electrode thereby allowing rescuers to obtain accurate depth compression feedback when CPR is performed on soft/ compressible surfaces. Dual sensor technology, utilized in the proposed OneStep Pediatric CPR MFE, has been reviewed and cleared by the agency with OneStep CPR II MFE (K133441).

As with the predicate device, the proposed electrode and wire harness with a ZOLL proprietary connector will have a pre-connect feature that enhances the user's ability to deliver immediate therapy. And like the predicate device, the OneStep Pediatric CPR electrode is also designed to support the defibrillator's self test and expiration date identification. Each electrode pad is structurally comprised of a solid hydrogel with a pure tin electrical conductive element having a polyethylene terephtalate (PET) backing with an adhesive perimeter suitable for coupling to patient skin during rescue and/or treatment.

Device Name: OneStep Pediatric CPR Multi-Function Electrode

Intended Use:

- Defibrillation
- Cardioversion
- Noninvasive Pacing
- ECG Monitoring
- CPR Feedback

For use with **ZOLL**® Defibrillators, such as:

- R Series
- X Series

By Trained Personnel only, Including:

- Physicians
- Nurses
- Paramedics

- Emergency Medical Technicians
- Cardiovascular Laboratory Technicians

The OneStep Pediatric CPR electrodes are indicated for use on a patient less than 8 years of age or weighing less than 55 lbs (25kg).

Substantial Equivalence – Non-Clinical Evidence:

The proposed **ZOLL OneStep Pediatric CPR** Multi-Function Electrode (MFE) is identical to the currently marketed **ZOLL OneStep Pediatric CPR** MFE (K120907) except that the proposed electrode introduces an additional motion sensor on the posterior pad which allows the users to obtain accurate compression depth feedback while performing CPR on soft/ compressible surfaces. The change is similar to one implemented for OneStep CPR II MFE (K133441).The intended use of the **OneStep Pediatric CPR** Multi-Function Electrodes as described in the Indications for Use and labeling has not changed as a result of this submission.

Substantial Equivalence – Clinical Evidence:

N/A - Clinical evidence was not necessary to show substantial equivalence

Comparison of Technological Characteristics

From a technological standpoint, the only difference between the proposed **ZOLL OneStep Pediatric CPR** Multi-Function Electrode (MFE) and the currently marketed **ZOLL OneStep Pediatric CPR** MFE (K120907) is the introduction of the dual sensor technology in the proposed device. Dual sensor technology, utilized in the proposed OneStep Pediatric CPR MFE, has been reviewed and cleared by the agency with OneStep CPR II MFE (K133441).

Performance Testing:

The **proposed OneStep Pediatric CPR** Multi-Function Electrode has been subjected to extensive performance testing to ensure the device meets all of its functional requirements and performance specifications as defined in applicable National/International recognized standards.

- EMC Testing in accordance with IEC 60601-1-2.
- Electrical, mechanical, bio-compatibility and simulated use testing per the applicable requirement of international recognized standards IEC 60601-1, IEC 60601-2-4, ISO 10993-1, ISO 10993-5 and ISO 10993-10.
- Testing to qualify the use of the electrode with R Series and X Series devices.
- Usability testing

Conclusion:

The information provided in this 510(k) demonstrates that the proposed **ZOLL OneStep Pediatric CPR** Multi-Function Electrode (MFE) is substantially equivalent to indicated commercially distributed devices with regard to performance, safety and effectiveness.